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User's Manual CPAP - AUTO - BILEVEL - BILEVEL ST20 and ST30

Art.-no.: 5000 0427

TREND II

User's manual

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The HOFFRICHTER GmbH reserves the right to amend or replace this user's manual without prior notice.

Please ensure that you are always working with the most current version of this user's manual. Should you have any questions, please contact the ventilation device provider, or check our information at www.hoffrichter.de.

The respiratory device may only be operated and maintained by trained personnel.

The following documents are available for TREND II in addition to this user's manual:

- Brief instructions for physicians and medical professionals
- Brief instructions for patients
- Service manual
- Hygiene concept

SERIAL NUMBER

Every HOFFRICHTER GmbH device is supplied with a serial number for traceability purposes.

Please enter your device's serial number here. You will find the serial number on the rating plate on the bottom of the device.

Serial number:	

Please always quote the serial number for all queries and complaints.

CONFORMITY



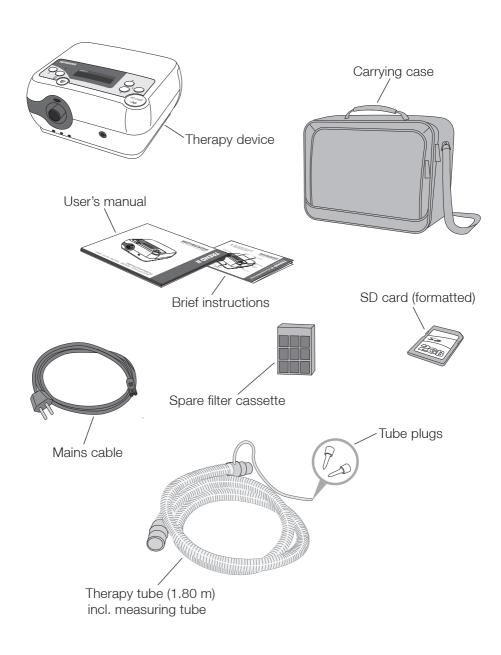
The device complies with the requirements of Directive 93/42/EEC.

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SCOPE OF DELIVERY



GENERAL

INFORMATION ON USER'S MANUAL

Read this user's manual through carefully before using the therapy device for the first time.

Follow the safety and cleaning instructions in particular.

Keep the manual in a safe place close to the device so that you can refer to it immediately if necessary.

SYMBOLS ON THE PACKAGING



Range of humidity for storage and transport



Range of ambient air pressure for storage and transport



Range of temperature for storage and transport

SYMBOLS ON THE RATING PLATE



Observe the warning and safety instructions in the user's manual.



BF application part



Protection class II (protective insulation)



CE conformity declaration



Follow the user's manual.



Manufacturer



Do not dispose of the device in the household waste. Please contact the relevant customer services department to find out how to dispose of the device properly.

SYMBOLS USED IN THIS USER'S MANUAL

Important information is denoted by symbols in this user's manual. Be sure to follow these instructions in order to avoid accidents, personal injury and material damage.

In addition, the local accident prevention regulations and general safety regulations in force in the area of use must be observed.



This symbol denotes general safety instructions. Follow these instructions to avoid accidents, personal injury or material damage.

A DANGER

This symbol denotes hazardous situations that lead to serious injuries or death.

♠ WARNING

This symbol denotes hazardous situations that may lead to serious injuries or death.

▲ CAUTION

This symbol denotes hazardous situations that may lead to moderately severe injuries.

NOTICE

This symbol denotes situations that may lead to material damage or damage to the device.

IMPORTANT

This symbol denotes information, tips and instructions for the efficient, error-free use of the device.

SAFETY INFORMATION

GENERAL SAFETY INSTRUCTIONS



- The device must only be used for your own CPAP therapy. which is prescribed by the physician.
- Use only accessories and spare parts tested and approved by the manufacturer.
- For operation and usage of the device at home, a respiratory mask specially adapted for the individual patient is required in addition to the therapy device with power cable and therapy tubing system. Only use masks that have been prescribed for your treatment by a physician.
- Only use the mask together with a respiratory therapy device and when the device is switched on.
- Unless specified otherwise, the mask and therapy tube must only be used by one patient.
- Only use the mask after instruction by a qualified medical person and clarify in particular the intake of medicines and possible contraindications and side effects associated with the use of the mask.
- If you are using oxygen with the CPAP therapy, observe the fire protection and safety regulations for using oxygen.
- Do not wear the mask if the therapy device is switched off because this could lead to breathing in air that has already been exhaled. Observe the respiratory mask manufacturer's instructions.
- Always ensure that the small hole in the mask or in the adapter between the mask and the tube is unobstructed so that the exhaled air that is loaded with CO₂ can escape.
- Observe the mask manufacturer's instructions.
- Please see your physician immediately if dryness of the mucous membranes in the nose and throat, sinus discomfort, ear ache, runny nose, over sensitive reactions of the skin, irritability, loss of voice, orientation or memory impairment occur when using the device.
- Inform your specialist dealer immediately if the device is not working properly.
- Check the device's alarm functions regularly (see page 59).

ELECTRICAL SAFETY



- Do not use the device if the housing or the cable of the device or the power supply are damaged.
- Always remove the power plug before cleaning.
- Do not open the device housing under any circumstances.
 Inform your specialist dealer if the device develops a fault.
- The use of accessories or power supplies not approved by us for the device may lead to increased emission of electromagnetic radiation or reduced resistence to interference.
- Protect the device from water and dampness.
- Never operate the device in damp places or in a bathroom.
- Do not put any containers full of liquid on the device.
- Do not reach for the device under any circumstances should it fall into water. Immediately unplug the power plug.
- Do not put the device near water containers (baths).

INSTALLATION REQUIREMENTS AND TRANSPORT



- Place the device near the bed. Ideally a firm, level surface on your bedside cabinet is suitable.
- Never put the device on a cupboard shelf or under the bed.
- Do not put the device with its back to a wall. Ensure that the air inlet is not covered.
- Ensure that the device is in a horizontal position, especially if it is connected to a humidifier.
- Ensure that the air can circulate properly round the device.
 Air circulation, particularly under and behind the device, must not be obstructed by furniture, curtains or cushions.
- Place the device in such a way that the mains plug is easily accessible so that it can be unplugged quickly in the event of a hazard.
- Do not put the device close to a source of heat.
- Place the device and accessories in such a position that they are not exposed to direct sunlight.
- The device must never be put near other devices or equipment such as defibrillators, diathermy units, mobile phones, microwaves, remote controlled toys, etc. Electromagnetic fields that exceed 3 V/m may adversely affect the operation of the TREND II.
- When used as a mobile unit, it must also be placed on a level, firm surface that has a raised edge so that the device cannot fall.
- During mobile use of the device, only operate it when the vehicle is stationary.

INSTRUCTIONS BEFORE COMMISSIONING



- Do not switch the device on if it has previously been in a very cold environment. Wait about 1 hour until the temperature has balanced out.
- Check the filter cassette regularly. Change the filter cassette as described on page 68. Never use the device without the filter cassette.
- Clean your mask system regularly and check all accessories, particularly the therapy tube, mask and headgear.
 When doing this, observe the manufacturer's safety and cleaning instructions.

USING OXYGEN

- Oxygen supports combustion. Therefore, observe the fire protection regulations applicable for using oxygen.
- Ensure that there is no grease on the oxygen fittings. Do not smoke and do not handle naked flames.
- Before the device is used, appropriate training must be carried out in the home environment.
- Please be sure to observe the user's manual of the manufacturer or distributor from whom you obtain the oxygen.
- Make sure that the distance between the oxygen source and device is at least 1 m.
- Have your distributor advise you about the use of oxygen.
- In any case, follow your physician's instructions.

INTENDED USE

The TREND II is used to treat obstructive sleep apnea in patients weighing more than 30 kg.

The device creates continuous, positive airway pressure to keep the upper respiratory tracts open.

The device is not suitable for use with patients undergoing artificial respiration.

▲ DANGER

This therapy device is not a life-supporting system.

The therapy pressure is administered via a respiratory mask which must be fitted with an exhalation valve to ensure that the exhaled air is discharged.

NOTICE

If an AquaTREND uni humidifier is connected to the device, the water in the humidifier must not contain any additives such as medicines, salts, aromatic oils or other substances.

CONTRAINDICATIONS

AWARNING

Respiratory therapy may be contraindicated for certain pre-existing conditions. Therefore, always talk to the physician treating you before starting the therapy.

Pre-existing conditions include:

- bullous lung diseases
- pneumothorax
- very low blood pressure
- pneumocephalus after open craniocerebral injury or other head injuries

In the event of inflammation of the paranasal sinuses or a middle-ear infection, it should be checked whether the therapy can continue. Please speak to your physician about this.

SIDE EFFECTS

There is the possibility of undesirable side effects occurring with respiratory therapy. Reasons for side effects occurring could be unsuitable therapy settings, not using the device properly or not following the cleaning instructions. Normally the side effects disappear when the causes have been eliminated.

You will find suitable counter measures for some side effects in the section "Troubleshooting" on page 71.

The following side effects may occur during therapy:

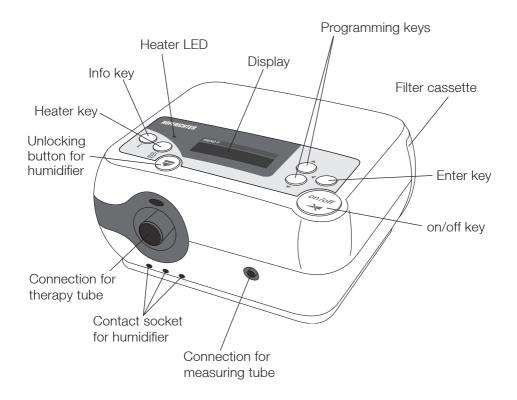
- Pain in the nose, the paranasal sinuses and the ears
- Dryness and irritation in the nose and throat
- Nose bleed, runny nose, sneezing, colds
- Irritated or dry eyes
- Reddening of the skin, swelling of the skin and pressure points in the mask area
- Difficulty breathing, claustrophobia
- Stomach problems because of air accumulating in the stomach

ACAUTION

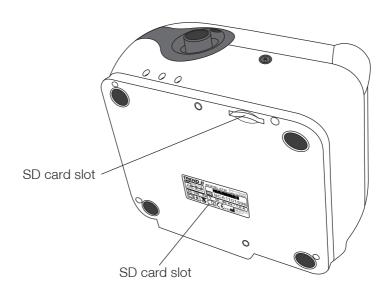
Please contact your physician for an explanation of the causes should these complaints persist.

DESCRIPTION OF DEVICE

HOUSING, DISPLAY AND CONTROL ELEMENTS







TECHNICAL DESCRIPTION

For all devices of the TREND II series the following characteristics apply:

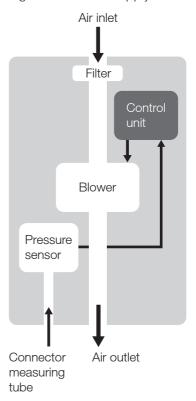
To generate the necessary pressure, the device is provided with an electronically controlled blower. In order to keep the stress for the patient as low as possible, the blower has been designed with a high reserve capacity and a quick control response.

The pressure is measured directly in the mask and constantly controlled by the device. Consequently, the breathing work for the patient is as easy as possible.

There are two separate tubings in the device. One is for respiratory air and one is for the convection air required for cooling the electronics.

The device contains a built-in microcontroller which controls all of its functions.

A quartz alarm clock further adds to the comfort when using the device. Further comfort functions include a soft start ramp, the automatic start-stop function and the adjustable display brightness. While passing through the device, the air is heated a little, so that it has a higher water absorbency. When indoor air is dry in winter, the mucous membranes in mouth and nose may become particularly dry.



This is unpleasant and may even cause infections in exceptional cases. For that reason, a therapy might require air humidification.

AquaTREND uni a clip-on humidifier is available as accessory for all TREND II devices.

If necessary, just click the humidifier onto the device. Remove it by pressing its release button.

The heater levels are set in the heater menu. The selected heater level is displayed as in the display of the device while the humidifier heating is switched on.

Press ON/OFF! Heat : 2 21:45

For more information please see your AquaTREND uni - User's manual or contact your specialized dealer.

POWER SUPPLY

Internal switched-mode power supply

For mains operation the TREND II has an internal switching power supply with a wide input range of 100 - 240 V alternating current (AC), 50 - 60 Hz. Thus it is possible to connect it to an energy supply anywhere in the world.

DC vehicle cable

For mobile use of the TREND II, e.g., in a truck or a caravan, it is possible to operate it with a 24 V direct current (DC). For this you will need the optionally available DC vehicle cable.

A WARNING

Only use the optional DC vehicle cable to connect the device to a DC power supply and do not connect the device to a PC while it is being used.

TREND II CPAP

The CPAP device is a therapy device for treating obstructive sleep apnea. For this purpose the device provides a continuous positive air pressure. Apart from the conventional CPAP-mode the device offers a proportional increase in pressure in the FLEX mode to the individual breath flow during inspiration and a pressure drop during the expiration. This intelligent method of pressure adjustment makes a careful therapy possible.

TREND II AUTO

Within a certain pressure range the device automatically controls the therapy pressure depending on the occurrence of respiratory events (APAP = Adaptive Positive Airway Pressure). In sleep phases with no events the therapy pressure is lowered. Starting obstructive events are treated effectively with a slight pressure increase.

For a high therapy comfort the therapy pressure should always be only as high as necessary and as low as possible.

The device can recognize the following respiratory events:

- Obstructive apnea
- Hypopnea
- Central apnea
- Snoring
- Normal respiration
- Increased airway resistance

The identification of the different respiratory events is achieved via 3 channels:

- 1. Measurement of any constriction of the respiratory tract
- 2. Detection of flow limitations by measuring the flow
- 3. Detection of snoring with the help of sound detection

The combined analysis of all results facilitates a very precise differentiation between obstructive and central events.

The device adjusts the therapy pressure according to the detected events as described below:

- Increase of pressure for obstructive events
- Decrease of pressure for central events and normal respiration

In addition, the pressure increase can be adjusted in 5 levels according to special requirements and to the individual patient comfort. These settings are performed by the physician with the help of the PC software TRENDset.

The TREND II AUTO offers a CPAP, APAP and FLEX mode. For APAP and FLEX mode, a pressure increase for inspiration and a pressure decrease for expiration can be set. Both pressure increase and decrease are following the individual

respiration flow proportionately. This intelligent method of pressure adjustment facilitates a careful therapy.

TREND II BILEVEL

The device has two different adjustable pressure levels. A higher level for inspiration and a lower level for expiration.

Trigger device

The respiration trigger detects the patients efforts to breath in and out and signals these efforts to the control device. A volume-based trigger can be set for inspiration, and a flow-based trigger for expiration. In conjunction with an optimum slope adjustment, this results in a therapy which is very comfortable for the patient and which gives the impression as if the device is following the natural respiration without any delay.

NOTICE

During the expiration phase a negative pressure (vacuum) will not be created.

CPAP-mode

The device provides continuous positive pressure for the therapy.

S-mode

Spontaneous trigger – the change from one pressure level to another is triggered by starting respiration of the patient only. When the inspiration flow ends, the pressure drops to the lower level set. In addition, a backup frequency (Backup freq) can be activated so that in the event of apnea, the patient continues to be ventilated with fixed parameters.

TREND II BILEVEL ST20 AND ST30

The device has two different adjustable pressure levels. A higher level for inspiration and a lower level for expiration.

Trigger device

The respiration trigger detects the patients efforts to breath in and out and signals these efforts to the control device. A volume-based trigger can be set for inspiration, and a flow-based trigger for expiration. In conjunction with an optimum slope adjustment, this results in a therapy which is very comfortable for the patient and which gives the impression as if the device is following the natural respiration without any delay.

The modes CPAP, S, ST and T are integrated in the device.

CPAP-mode

The device provides continuous positive pressure for the therapy.

S-mode

Spontaneous trigger – the change from one pressure level to another is triggered by starting respiration of the patient only. When the inspiration flow ends, the pressure drops to the lower level set. In addition, a backup frequency (Backup freq) can be activated so that in the event of apnea, the patient continues to be ventilated with fixed parameters.

ST-mode

Spontaneous breathing and Timed – as long as the patient is breathing spontaneously the device is operating in the S-mode. If the patient stops breathing, the device automatically switches to the T mode and ventilates the patient with the set frequency. The delay time after which the device switches into the T-mode is adjustable.

T-mode

Timed respiration with prescribed, set inspiration time. If the trigger function is deactivated the patient is ventilated according to the set parameters. If the trigger function is activated the device accepts only spontaneous trigger signals in the expiration phase.

NOTICE

During the expiration phase a negative pressure (vacuum) will not be created.

USING THE DEVICE

COMMISSIONING

ACAUTION

Before commissioning the device, read the section "Safety information" (from page 10). The device must not be operated without a filter cassette because this could damage your health.

1. After having set up the device properly, connect the device using the supplied power cord, with the socket outlet.



- 2. The device displays a welcoming message, the software version and the current number of treatment hours. Thereafter, the display shows the date and time.
- 3. Connect the therapy tube to the air outlet.



4. Connect the therapy tube to the mask.



5. Also connect the measuring tube to the measuring tube connection.



6. Put on the mask. If you have selected the automatic mode, the device will start on your first breath. In the manual mode, press the on/off key to start the device.



- 7. The device first of all runs at maximum pressure for the time selected by you for the mask test. You should now properly seat the mask in order to eliminate any potential leaks.
- 8. Place the tube such that it does not exert any pulling action on the mask while you are lying down
- 9. Breathe deeply and calmly. If you have activated the soft start function, the device initially reduces the pressure after completion of the mask test and will then slowly increase the pressure automatically to the prescribed value, allowing you to fall asleep at a lower pressure.

IMPORTANT

In the section "Device functions" (from page 28) read how you can adapt the times for soft start and the mask test to suit your personal requirements.

ENDING THERAPY

To end the therapy, press the on/off key.

If you are using an SD card, the therapy data is saved on the SD card after the therapy is ended. During this time, the message "Do not remove the SD card" is shown on the display.

Do not remove the SD card

NOTICE

On no account remove the SD card during saving. This could lead to loss of data or damage to the SD card.

SWITCHING OFF THE DEVICE

Ensure that the device is in standby mode. Then unplug the power plug.

STANDBY MODE

If the turbine is switched off, the device switches to standby mode (discernable on the display with date and time).

Press ON/OFF! 25.May.11 12:20

The TREND II can be kept in standby mode permanently. This does not harm it.

USING OXYGEN

A DANGER

If oxygen is using the therapy setting must be set, that no backflow of oxygen takes place into the device.

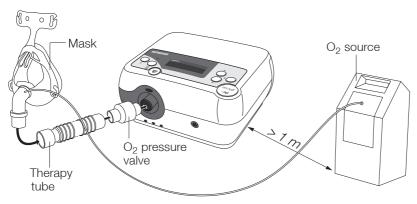
A WARNING

Before using oxygen, it is essential to read the safety information on page 13.

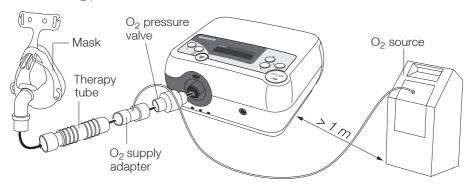
When supplying oxygen, please use a kink-resistant tube made of a medically approved material. In order to prevent back flow of oxygen into the device, we recommend the use of an O_2 pessure valve.

There are two variants to supply oxygen.

Variant 1: Supplying oxygen directly in the mask



Variant 2: Supplying oxygen via an adapter between therapy tube and O₂ pressure valve



The O_2 supply adapter and O_2 pressure valve you can order as accessory (see page 75).

Proceed as follows when using oxygen:

AWARNING

If the device is in standby mode or switched off, the oxygen supply must always be switched off.

- 1. Before starting the treatment, check that the tube connections are fitted correctly.
- 2. First of all, switch the device on and then the oxygen supply.
- 3. Check whether the "Auto off" automatic mode is active. If not, program it as described on page 41.
- 4. Switch off the oxygen supply before switching the device off.

NOTICE

Using oxygen influences the therapy pressure. Therefore we recommend to inclose oxygen in the therapy pressure determination / titration process, for every patient who's therapy is intended to include an oxygen supply.

DEVICE FUNCTIONS

There are three keys for programming the TREND II functions.

- ▲ = Programming key
- ▼ = Programming key
- Enter key

The display has two lines. Using the programming keys \triangle and ∇ , you can select the line to be displayed. The triangular symbol \triangleright preceding the line indicates that this line has been selected.



Example: Pressure

IMPORTANT

If you do not press any key for 30 seconds while programming, the programming mode is automatically exited for safety reasons.

Unless the changed value is confirmed with the enter key when the programming mode is exited, the original value remains as it is.

If you select the line Exit Menu and then press the enter key ◀, programming is ended.

The device has three different menus:

- Info-Menu
 In this menu the set parameters can be displayed.
- 2. Patient-Menu
 In this menu the patient can change settings.
- 3. Clinic-Menu
 In this menu, only a physician or service technicians can change settings.

Use the programming key \blacktriangle for scrolling within the menus. The sequence of the menu structure is shown in the table from page 29.

INFO-MENU

By pressing the info key i you get to the Info-Menu. By pressing the progaming keys ▲ and ▼ you can see the next parameters. For the parameters "Use", "Al" or "AHI" and "Leak", pressing the enter key ◀ enables you to display average values across different periods of time. To exit the Info-Menu select the line Exit Menu and then press the enter key ◀. If you do not press any keys for 30 seconds the device will automatically switch back to the operating mode.

The following table shows which parameters are displayed in the Info menu, depending on the set mode or device type.

	Mode					
	CPAP	FLEX	APAP	BILEVEL	BILEVEL	BILEVEL
Parameter				S	ST	Т
Use[D] Use[W] Use[M] Use[6M] Use[Y]	•	•	•	•	•	•
$\begin{array}{ccc} AI[D]^1 & \blacktriangleleft \\ AI[W]^1 & \blacktriangleleft \\ AI[M]^1 & \blacktriangleleft \\ AI[6M]^1 & \blacktriangleleft \\ AI[Y]^1 & \blacktriangleleft \end{array}$	•	•	•	•	•	•
Leak[D]	•	•	•	•	•	•
Therapy	•	•	•	•	•	•
Filter	•	•	•	•	•	•
Ramp	•	•	•	•	•	•
P-Ramp	•	•	•	•	•	•
Mode	•	•	•	•	•	•
Press.	•	•	-	-	-	-
I-Pres.	-	-	-	•	•	•
E-Pres.	-	-	-	•	•	•
P-Start	-	-	•	-	-	-
P-Min	-	-	•	-	-	-
P-Max	-	-	•	-	-	-
I-FLEX	-	•	•	-	-	-
E-FLEX	-	•	•	-	-	-
I-Slope	-	-	-	•	•	•

	Mode					
Parameter	CPAP	FLEX	APAP	BILEVEL S	BILEVEL ST	BILEVEL T
E-Slope	-	-	-	•	•	•
Trigger	-	-	-	-	-	•
I-Trigger	-	-	-	•	•	• 4
E-Trigger	-	-	-	•	•	-
Frequency	-	-	-	-	•	•
Backup freq	-	-	-	•	-	-
I:E	-	-	-	=	•	•
Delay Time	-	-	-	-	•	-
VT min	-	-	-	• 3	• 3	• 3
P-addit.	-	-	-	• 5	• 5	• 5
TI min	-	-	-	• 6	• 6	-
TI max	-	-	-	• 6	• 6	=.
Low MV ²	-	-	-	• 3	• 3	• 3
Apnea ²	-	-	-	● 3, 7	-	-

■ Next parameter is displayed by pressing the enter key

¹ in TREND II CPAP and TREND II AUTO "AHI" (Apnea-Hypopnea-Index) instead of "AI" is displayed

² only available when activated by physician

³ only TREND II BILEVEL ST30

⁴ only if trigger is "ON"

⁵ cannot be set if VT min is "OFF"

 $^{\,}$ 6 $\,$ only TREND II BILEVEL ST20 and ST30 $\,$

⁷ only if Backup frequency is "OFF"

MEANING OF THE PARAMETERS IN THE INFO MENU

MEANING OF THE PARAMETERS IN THE INFO MENU					
▶Use[D]8∎0h Exit Menu	Use[D] Shows the average operating time of the last therapy day ¹				
>Use[W]7.5h Exit Menu	Use[W] Shows the average operating time, per therapy day, in the last week				
>Use[M]8.0h Exit Menu	Use[M] Shows the average operating time, per therapy day ¹ , in the last month				
►Use[6M]8.5h Exit Menu	Use[6M] Shows the total operating time, per therapy day ¹ , in the last 6 months				
>Use[Y]8.5h Exit Menu	Use[Y] Shows the average operating time, per therapy day ¹ , in the last year				
▶AHI[D]9.2 Exit Menu	AI[D] Shows the apnea index of the last night				
►A [W]5.9 Exit Menu	AI[W] ² Shows the apnea index of the last week				
►AI[M]6.5 Exit Menu	AI[M] ² Shows the apnea index of the last month				

Al[Y].....6.4 Al[Y]²
Exit Menu Shows

Exit Menu

Shows the apnea index of the last year

Shows the apnea index of the last 6 months

- 1 from 12.00 to 12.00 o'clock
- 2 in TREND II CPAP and TREND II AUTO "AHI" (Apnea-Hypopnea-Index) instead of "AI" is displayed

AI[6M]2



Leak[D]

Shows the percentage of the operating time in which increased leakage was detected, over the period of the last therapy day¹



Leak[W]

Shows the percentage of the operating time in which increased leakage was detected, over the period of the last week



Leak[M]

Shows the percentage of the operating time in which increased leakage was detected, over the period of the last month



Leak[6M]

Shows the percentage of the operating time in which increased leakage was detected, over the period of the last 6 months



Leak[Y]

Shows the percentage of the operating time in which increased leakage was detected, over the period of the last year



Therapy

Shows the total therapy time of the device



Filter

Shows the time since the last filter change



Ramp

Shows the remaining time of the soft start ramp



P-Ramp

Shows the ramp start pressure



Mode

Shows the selected mode

1 from 12.00 to 12.00 o'clock

≯Press7.5hPa Exit Menu	Press. (only in modes CPAP and FLEX) Shows the selected therapy pressure
≯P-Start7.5hPa Exit Menu	P-Start (only in mode APAP) Shows the selected start pressure
≯P-Min5.0hPa Exit Menu	P-Min (only in mode APAP) Shows the selected minimum pressure
≯P-Max10.0hPa Exit Menu	P-Max (only in mode APAP) Shows the selected maximum pressure
►1-FLEX3 Exit Menu	I-FLEX-Level (only in modes APAP and FLEX) Shows the selected I-FLEX-Level
►E-FLEX3 Exit Menu	E-FLEX-Level (only in modes APAP and FLEX) Shows the selected E-FLEX-Level
≻l-Pres10.0hPa Exit Menu	I-Pres. (only in modes S, T and ST) Shows the selected inspiration pressure
≯E-Pres6.0hPa Exit Menu	E-Pres. (only in modes S, T and ST) Shows the selected expiration pressure
≻I-Slope3s Exit Menu	I-Slope (only in modes S, T and ST) Shows the selected inspiration slope
≻E-Slope3s Exit Menu	E-Slope (only in modes S, T and ST) Shows the selected expiration slope
▶TrisserOFF Exit Menu	Trigger (only in mode T) Shows if the inspiration trigger is activated or not
≻l-Trisser2 Exit Menu	I-Trigger (only in modes S, T and ST) Shows the selected inspiration trigger threshold
▶E-Trisser2 Exit Menu	E-Trigger (only in modes S and ST) Shows the selected expiration trigger threshold

▶Frequency12bpm
Exit Menu

Frequency (only in modes T and ST)

Shows the selected number of breaths per minute



Delay Time (only in mode ST)

Shows the delay for switching from S-mode to T-mode



Backup freq (only in mode S in TREND II BILE-VEL, BILEVEL ST20 and ST30)

Shows whether the backup frequency is switched on or not



I:E (only in modes T and ST)

Shows the inspiration duration and the ratio of inspiration to expiration

▶VT min.....200ml Exit Menu VT min (only ST30 in mode ST)

Shows the target volume per breath

▶P-addit...3.0hPa Exit Menu P-addit. (only ST30 in mode ST)

Shows the pressure that is added in order to reach the target volume

▶T| min......1.2s Exit Menu TI min (only ST30 in modes S and ST) Shows the minimum inspiration time

▶TI max......3.0s Exit Menu TI max (only ST30 in modes S and ST) Shows the maximum inspiration time



Low MV (only ST30 in modes S, T and ST)

Shows whether the alarm for too low respiratory minute volume "Low MV" is active or deactivated



Apnea (only ST30 in mode S, if backup frequency "OFF")

Shows whether the "Apnea" alarm is active or deactivated

PATIENT-MENU

Press and hold the enter key ◀ (at least 1 second) to move to the programming mode. The Patient-Menu will now appear on the display.

The following table shows which parameters can be set in the Patient-menu, depending on the device type.

Device Parameter	CPAP	AUTO	BILEVEL	BILEVEL ST20	BILEVEL ST30
Wake Time	•	•	•	•	•
Delete Filter	•	•	•	•	•
Mask	-	•	-	-	-
Ramp	•	•	•	•	•
Mask Test	•	•	•	•	•
Auto	•	•	•	•	•
Display Vt	•	•	•	•	•
Brightness	•	•	•	•	•
Date	•	•	•	•	•
Time	•	•	•	•	•

SETTING PARAMETERS AND THEIR MEANING

Wake Time



The wake time can be set or changed here.

To set the wake time, first go to the Patient-menu (hold down the enter key ◀ It can now be changed using the programming keys ▲ and ▼. After pressing can change it using the programming keys ▲ and ▼. Pressing the enter key ■ again ends the input and you get back to the menu. Changing the wake time will automatically activate the alarm clock.

After leaving the menu the alarm clock can be activated and deactivated with the help of the programming keys \blacktriangle and \blacktriangledown . Press programming key \blacktriangle to activate the alarm function. The display briefly shows the wake up time allowing you to verify it.

Press ON/OFF! 07:00 Alarm <u>ON</u>

After that a bell symbol in front of the time display shows that the wake alarm function is activated.

Press ON/OFF! 25.May.11 *12:20

Press the programming key ▼ to deactivate the wake alarm function. The bell symbol disappears.

Press ON/OFF! Alarm Clock OFF

Delete Filter



In this menu item the filter counter can be reset. This function should be used at every filter change so that always a current value is displayed.

To reset the filter counter, go to the Patient-Menu (press the enter key ◀ key for approx. 1 second), then select **Delete Filter** with the programming keys ▲ and ▼. Press the enter key ◀. The system will now ask you whether you are sure that you want to perform a reset.

Press the enter key \blacktriangleleft to perform the reset. Now the filter counter is reset to zero. If you do not want to reset the filter counter, leave the menu using the programming keys \blacktriangle and \blacktriangledown or wait until the system leaves the menu item automatically.

Mask

(only in mode APAP in TREND II AUTO)



In this menu item the type of mask can be chosen. This is important for the correct function of the therapy device. You can choose between Nose and Nose/Mouth:

- Choose Nose for all nasal masks and pillow masks.
- Choose Nose/Mouth for all nasal/mouth masks.

To select the type of mask, first go to the Patient-menu (hold down the enter key ◀ for approx. 1 second). Then select Mask using the programming keys ▲ and ▼ and press the enter key ◀ to change the setting.

Ramp



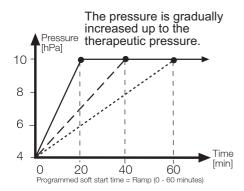
Whenever the blower has been started, the microcontroller of the device checks whether a soft start ramp has been programmed. While the programmed time elapses, the soft start function increases the pressure from an adjustable initial ramp pressure (P-Ramp) up to the pressure prescribed, thus allowing you to fall asleep more easily.

In particular if you are not yet used to the respiration therapy the soft start can help you get accustomed to the device and fall asleep easily.

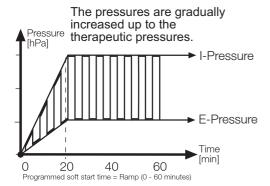
The device allows delay times ranging from zero (the prescribed therapy pressure is applied at once) to 60 minutes (the prescribed therapy pressure is built up within 60 minutes).

The initial ramp pressure (P-Ramp) can be set by health professionals within a range from 4 hPa to the pressure prescribed.

To set the ramp, first go to the Patient-Menu (press the enter key \blacktriangleleft for approx. 1 second), then select Ramp with the programming keys \blacktriangle and \blacktriangledown . Press the enter key \blacktriangleleft . Now select the desired time using the programming keys \blacktriangle and \blacktriangledown . Press enter key \blacktriangleleft to confirm.



BILEVEL S, ST and T



Mask Test

▶Mask Test.....30s Exit Menu

This parameter determines the time when the device performs a mask test.

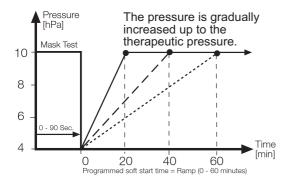
To ensure that the mask is tight while the pressure slowly increases in the soft start ramp even with higher pressures, you can program a mask testing time from 5 to 90 seconds in 5-second intervals. This mask test is carried out before the ramp is started. It checks whether the mask is tight even under the maximum therapy pressure.

The following table shows for every model, how the pressure during mask test is calculated subject to the mode that has been set.

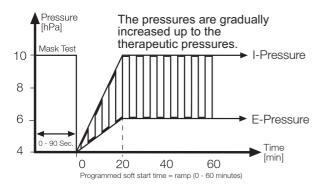
Mode Device	CPAP	FLEX	APAP	BILEVEL S	BILEVEL ST	BILEVEL T
TREND II CPAP	Press.	Press. + I-FLEX	-	-	-	-
TREND II AUTO	Press.	Press. + I-FLEX	P-Max + I-FLEX	-	-	-
TREND II BILEVEL	Press.	-	-	I-Pres.	-	-
TREND II BILEVEL ST20	Press.	-	-	I-Pres.	I-Pres.	I-Pres.
TREND II BILEVEL ST30	Press.	-	-	I-Pres. + P-addit.	I-Pres. + P-addit.	I-Pres. + P-addit.

To set the mask test, first go to the Patient-Menu (press the enter key ◀ for approx. 1 second), then select Mask Test with the programming keys ▲ and ▼. Press the enter key ◀. Now select the desired time using the programming keys ▲ and ▼. Press ◀ to confirm.

CPAP, FLEX and APAP



BILEVEL S, ST and T



Auto

The automatic mode provides three settings (OFF, Start/Stop, Start):

1. Auto OFF (with mask alarm)



If you set "Auto OFF" the device must be turned on in the evening and turned off in the morning with the on/off key. If the mask slips off your face or a leak occurs while you are asleep, a visual and audible warning is emitted (mask alarm).

Mask Alarm....10s Check Mask!

2. Auto Start/Stop



If you set "Auto Start/Stop", you must simply put the mask on your face.

Once you start breathing, the turbine of the device is turned on. If you take the mask off, the turbine is automatically turned off after a delay time of 5 seconds. In the automatic mode, the turbine is turned off even if the mask or the tube slips off unnoticed during the night.

3. Auto Start (with mask alarm)

The third option that can be selected is the "Auto Start" mode.



Once you start breathing, the turbine of the device is turned on. If the mask slips off your face or a leak occurs while you are asleep, a visual and audible warning is emitted (mask alarm).

However, the turbine is not switched off. It can only be switched off by pressing the on/off key.

IMPORTANT

The automatic function can be deactivated in the TREND II BILEVEL ST20 and ST30 with the PC software from the medical staff.

The device can be switched on or off in every mode by pressing the on/ off key.

To set the automatic function, first go to the Patient-menu (hold down the enter key ◀ for approx. 1 second). Then select **Auto** using the programming keys ▲ and ▼. Press the enter key ◀ to change the setting.

Display Vt



Here, you can set whether the tidal volume and the respiratory status (S=spontaneous, T=timed [only in ST mode, and in S mode when Backup frequency is "ON"]) are displayed during therapy.

To activate or deactivate the display of the tidal volume, first go to the Patient-Menu (press the enter key ◀ for approx. 1 second). Then select Display ¼ to using the programming keys ▲ and ▼ and press the enter key ◀ to set the desired setting ("ON" or "OFF").

IMPORTANT

The display of the tidal volume during the therapy replaces the display of the date. The alarm clock is still active.

Brightness



In this menu item you can set the brightness of the display.

To set the brightness of the display, first go to the Patient-menu (hold down the enter key \blacktriangleleft for approx. 1 second). Then select **Brightness** using the programming keys \blacktriangle and \blacktriangledown . After pressing the enter key \blacktriangleleft the currently set brightness will flash and can then be adjusted using the programming keys \blacktriangle and \blacktriangledown in intervals of 10 %. Press enter key \blacktriangleleft for accepting the selected brightness. If no key is pressed for 30 seconds the device will reset the brightness to the old value.

After pressing any key the brightness of the display will automatically switch to 100 % for better visibility.

Date



Use this menu item to set the date.

To set the date, first go to the Patient-menu (hold down the enter key \blacktriangleleft for approx. 1 second). Then select \square at e using the programming keys \triangle and ∇ . After using the enter key \blacktriangleleft the year will flash and can be set using the programming keys \triangle and ∇ . After using the enter key \blacktriangleleft again the month will flash and can be set using the programming keys \triangle and ∇ . After using the enter key \blacktriangleleft again the day will flash and can be set using the programming keys \triangle and ∇ . Press the enter key \blacktriangleleft again to accept the set date.

Time



Use this menu item to set the time.

To set the time, first go to the Patient-menu (hold down the enter key \blacktriangleleft for approx. 1 second). Then select **Tirne** using the programming keys \blacktriangle and \blacktriangledown . After pressing the enter key \blacktriangleleft the hour will flash and can be set using the programming keys \blacktriangle and \blacktriangledown . After pressing the enter key \blacktriangleleft again the minutes will flash and can be set using the programming keys \blacktriangle and \blacktriangledown . Press the enter key \blacktriangleleft again to accept the set time.

With its built-in battery, the internal clock has a reserve power of 8 years without connection to the external power supply.

CLINIC-MENU

In addition to the parameters in the Clinic-Menu, in the Clinic-Menu parameters relevant for the therapy can be set. This menu is used only by health and service professionals. Some parameters are protected by a PIN code in order to prevent incorrect parameters being entered.

ACAUTION

Please do not try to find out the PIN. If you are in doubt as to whether the set parameters are correct, please consult your physician.

The following table shows which parameters can be set in the Clinic-menu, depending on the device type.

	Mode					
Davassatav	CPAP	FLEX	APAP	BILEVEL	BILEVEL	BILEVEL
Parameter Mode ¹	•	•	•	S	ST •	T •
Press. ¹	•	•	•	•		•
	•	•	-	-	-	-
P-Start ¹ ◀ P-Min ¹ ◀ P-Max ¹	-	-	•	-	-	-
I-FLEX¹ ◀ E-FLEX¹	-	•	•	-	-	-
Mask	-	-	•	-	-	-
I-Pres. ¹	-	-	-	•	•	•
Trigger ¹	-	-	-	=	-	•
I-Trigger ¹ ◀ E-Trigger ¹	-	-	-	•	•	• 2
Frequency ¹ ◀ I:E ¹ ◀ Delay Time ¹	-	-	-	-	•	•
Backup freq ¹	-	-	-	•	-	-
VT min ¹ ◀ P-addit. ¹	-	-	-	• 5	• 5	• 5
TI min ¹ ◀ TI max ¹	-	-	-	• 3	• 3	-
Ramp ◀ P-Ramp	•	•	•	•	•	•
Mask Test	•	•	•	•	•	•
Auto	•	•	•	•	•	•
Display Vt	•	•	•	•	•	•

			Mc	ode		
Parameter	CPAP	FLEX	APAP	BILEVEL S	BILEVEL ST	BILEVEL T
Low MV ¹ ◀ Apnea ^{1, 4}	-	-	-	• 5	• 5	● 5
Brightness	•	•	•	•	•	•
Language	•	•	•	•	•	•
P-Unit	•	•	•	•	•	•
Turbine ◀ Filter ◀ Therapy ◀ Standby	•	•	•	•	•	•
Delete Filter	•	•	•	•	•	•
Date	•	•	•	•	•	•
Time	•	•	•	•	•	•
Wake Time	•	•	•	•	•	•

■ Next parameter is displayed by pressing the enter key

To prevent incorrect parameters being entered, it is necessary to enter a PIN. This PIN is known to your physician and specialist dealer

² E-Trigger not in T mode, I-Trigger only if trigger is "ON"

³ only TREND II BILEVEL ST20 and ST30

⁴ Apnea only in mode S, if Backup frequency is "OFF"

⁵ only TREND II BILEVEL ST30

THERAPY-RELEVANT PARAMETERS AND THEIR MEANING.

Mode



The devices can be operated in different modes. The following table shows which modes are available for your device.

Mode Device type	CPAP	FLEX	APAP	BILEVEL S	BILEVEL ST	BILEVEL T
TREND II CPAP	•	•	-	-	-	-
TREND II AUTO	•	•	•	-	-	-
TREND II BILEVEL	•	-	-	•	-	-
TREND II BILEVEL ST20	•	-	-	•	•	•
TREND II BILEVEL ST30	•	-	-	•	•	•

To set the mode, first go to the Clinic-menu. Then select Mode using the programming keys ▲ and ▼. Press the enter key ◀.

Now the device will prompt you to enter the PIN.



The first digit is flashing. Enter the first digit of the PIN with the help of the programming keys ▲ and ▼. After pressing the enter key ◀ the second digit will flash. Enter the second digit of the PIN with the help of the programming keys ▲ and ▼, and proceed as described for the first digit. Enter the third digit accordingly. After entering the last digit of the PIN you can switch between the modes by pressing the enter key ◀. Leave the menu once the desired mode is selected. The device will then save the new mode.

Press (only in modes CPAP and FLEX)



To set the pressure, first go to the Clinic-menu. Then select Pressure using the programming keys ▲ and ▼. Press the enter key ◀. Now the device will prompt you to enter the PIN. The first digit is flashing. Enter the first digit of the PIN with the help of the programming keys ▲ and ▼. After pressing the enter key ■ the second digit will flash. Enter the second digit of the PIN with the help of the programming keys ▲ and ▼ keys, and proceed as described for the first digit. Enter the third digit accordingly. After entering the last digit of the PIN you can set the pressure using the programming keys ▲ and ▼. Then confirm the selected pressure by pressing the enter keys ◀.

P-Start (only in mode APAP)

To set the P-Start, first go to the Clinic-menu. Then select P-Start using the programming keys \blacktriangle and \blacktriangledown . Press the enter key \blacktriangleleft . Now the device will prompt you to enter the PIN. By using the programming keys \blacktriangle and \blacktriangledown you can now set the start pressure. Confirm with the enter key \blacktriangleleft . Next the parameter P-Min is set.

P-Min (only in mode APAP)

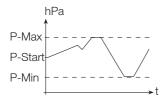
First set the P-Start. Then set the minimum pressure using the programming keys ▲ and ▼. Confirm with the enter key ◀. Next the parameter P-Max is set.

IMPORTANT

Therapy pressure may – depending on the set E-FLEX level – be falling up to 3 hPa below the value set for P-Min, yet never below 4hPa.

P-Max (only in mode APAP)

First set the P-Start and P-Min. Then set the maximum pressure using the programming keys ▲ and ▼. Confirm with the enter key ◀.



IMPORTANT

Therapy pressure may – depending on the set I-FLEX level – be rising up to 3 hPa above the value set for P-Max, yet never above 20 hPa.

I-FLEX (only in modes APAP und FLEX)



The I-FLEX settings (0 - 3) are for individual adjustment to the patients breathing flow:

- I-FLEX 0 = no pressure support ($\triangle P_{max} = 0 \text{ hPa}$)
- I-FLEX 1 = low pressure support (△Pmax ≤ 1 hPa)
- I-FLEX 2 = medium pressure support (△Pmax ≤ 2 hPa)
- I-FLEX 3 = high pressure support (△Pmax ≤ 3 hPa)

The value of pressure increase depends on the value of the breathing flow, the set I-FLEX and the set therapy pressure.

To set I-FLEX, first go to the Clinic-menu. Then select I-FLEX using the programming keys ▲ and ▼. Press the enter key ◀. Now the device will prompt you to enter the PIN. The first digit is flashing. Enter the first digit of the PIN with the help of the programming keys ▲ and ▼. After pressing the enter key ◀ the second digit will flash. Proceed with entering the remaining digits as you did the first.

After entering the last digit of the PIN you can set I-FLEX using the programming keys ▲ and ▼. Then confirm the selected level by pressing the enter key ■. Next the parameter E-FLEX is set.

IMPORTANT

By setting I-FLEX to 1-3 the value for P-Max can be exceeded during therapy.

E-FLEX (only in modes APAP und FLEX)

The E-FLEX settings (0-3) are for individual adjustment to the patients breathing flow:

- E-FLEX $0 = \text{no pressure support } (\triangle Pmax = 0 \text{ hPa})$
- E-FLEX 1 = low pressure support ($\triangle Pmax \le 1 hPa$)
- E-FLEX 2 = medium pressure support (△Pmax ≤ 2 hPa)
- E-FLEX 3 = high pressure support (△Pmax ≤ 3 hPa)

The value of pressure decrease depends on the value of the breathing flow, the set E-FLEX and the set therapy pressure.

To change E-FLEX, set I-FLEX first. Afterwards you can set E-FLEX using the programming keys ▲ and ▼. Confirm the selected level by pressing the enter key ◀.

IMPORTANT

By setting E-FLEX to 1-3 the value for P-Min can be undercut during therapy.

I-Pres. (only in modes S, T and ST)
Pressure during inspiration

▶|-Pres...10.0hPa Exit Menu

To set the I-Pressure, first go to the Clinic-menu. Then select I-Press using the programming keys \blacktriangle and \blacktriangledown . Press the enter key \blacktriangleleft . Now the device will prompt you to enter the PIN. The first digit is flashing. Enter the first digit of the PIN with the help of the programming keys \blacktriangle and \blacktriangledown . After pressing the enter key \blacktriangleleft the second digit will flash. Enter the second digit of the PIN with the help of the programming keys \blacktriangle and \blacktriangledown , and proceed as described for the first digit. Enter the third digit accordingly. After entering the last digit of the PIN you can set the pressure using the programming keys \blacktriangle and \blacktriangledown . Then confirm the selected pressure by pressing the enter key \blacktriangleleft . Next the parameter E-Pressure is set.

E-Pres. (only in modes S, T and ST)

Pressure during expiration



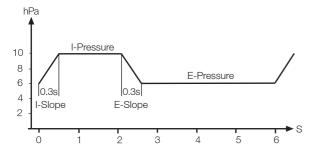
First set the I-Pressure. Then set the desired pressure using the programming keys \triangle and ∇ . Press enter key \triangleleft to confirm. Next the parameter I-Slope is set.

I-Slope (only in modes S, T and ST)

Time of pressure increase from E-Pressure to I-Pressure (pressure increase rate)



First set the I-Pressure and E-Pressure. Then set the desired time using the programming keys \blacktriangle and \blacktriangledown . Press enter key \blacktriangleleft to confirm. Next the parameter E-Slope is set.



E-Slope (only in modes S, T and ST)

Time of pressure decrease from I-Pressure to E-Pressure (pressure decrease rate)



First set the I-Pressure, E-Pressure and the I-Slope. Then set the desired time using the programming keys \blacktriangle and \blacktriangledown . Press enter key \blacktriangleleft to confirm.

Trigger (only in mode T)



To set the Trigger, first go to the Clinic-menu. Then select **Trigger** using the programming keys ▲ and ▼. Press the enter key ◀. Now the device will prompt you to enter the PIN. Pressing the enter key ◀ again changes the setting from "OFF" to "ON" and vice versa.

I-Trigger (only in modes S, T and ST)



The I-Trigger depends on the volume and determines the sensitivity for detecting inspiration. It can be set to three levels.

1	10 ml
2	15 ml
3	25 ml

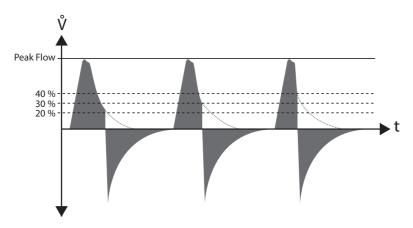
To set the I-Trigger, first go to the Clinic-menu. Then select **I-Trigger** using the programming keys \blacktriangle and \blacktriangledown . Press the enter key \blacktriangleleft . Now the device will prompt you to enter the PIN. Now select the desired level by pressing the keys \blacktriangle and \blacktriangledown . Press enter key \blacktriangleleft to confirm. Next the parameter E-Trigger is set.

E-Trigger (only in modes S and ST)



The setting of the E-Trigger defines the percentage of the peak flow at which the ventilator switches over to expiration. It can be set to three levels.

Level 1	40 % of peak flow
Level 2	30 % of peak flow
Level 3	20 % of peak flow



First set the I-Trigger. Then set the desired level using the programming keys ▲ and ▼. Press enter key ◀ to confirm.

Frequency (only in modes T and ST)



The frequency determines the breathes per minute (only in mode T or in mode ST with apnea).

To set the frequency, first go to the Clinic-menu. Then select **Frequency** using the programming keys ▲ and ▼. Now the device will prompt you to enter the PIN. After entering the PIN set the desired frequency using the programming keys \blacktriangle and \blacktriangledown . You can set values from 5 bpm to 30 bpm in 1 bpm-intervals.

I:E (only in modes T and ST)



The ratio I:E determines the ratio of inspiration to expiration.

First set the frequency. Then set the desired inspiration time using the programming keys ▲ and ▼. Values between 0.4 s and 8.0 s can be set in 0.1 s steps. To confirm, press the enter key ◀. The ratio I:E depends on the set inspiration time. The delay time parameter is set next.

Delay Time (only in mode ST)



The delay time is the time after which the device switches from S-mode into T-mode in the event of breath failure.

First set the frequency and the inspiration time (I:E). Then set the delay time using the programming keys ▲ and ▼. Press enter key ◀ to confirm. You can set values from 0 sec to 20 sec in 1 sec-intervals.

Language



The device can emit display messages in German (DEU), English (ENG), Greek (ELL), Spanish (SPA), French (FRA), Italian (ITA), Turkish (TUR), Polish (PLK) and Portuguese (POR).

To set the language, first go to the Clinic-menu. Then select **Language** using the programming keys ▲ and ▼. Press the enter key ◀. Each time you press the key another language will appear. Leave the menu once the desired language is selected. The device will then save the new language.

P-Unit



The device can show the pressure in the pressure units hectopascal (hPa), millibar (mbar), and centimeters of water (cm = cm H_2O).

To set the unit of pressure, first go to the Clinic-menu. Then select **P**⁻**Unit** using the programming keys ▲ and ▼. Press the enter key ◀. Each time you press the key another pressure unit will appear. Leave the menu once the desired pressure unit is selected. The device will then save the new unit.

ACAUTION

When changing the pressure unit from hPa or mbar to cmH₂O, the pressure will slightly change. Conversion: 1 hPa \triangleq 1 mbar \triangleq 1.02 cmH₂O Example: At 8 cmH₂O the pressure is 7.8456 hPa or mbar.

Turbine

This menu item shows the total operating time of the turbine, the filter, and the therapy time.

Turbine



The counter indicates the total turbine running time.

Filter



The counter indicates the operating hours of the filter since the last reset.

Therapy



The counter indicates the operating time with the therapy pressure applied.

Standby



This counter indicates the time the device was connected to the power supply.

To display the counter, first go to the Clinic-menu. Then select **Turbine** using the programming keys ▲ and ▼. Press the enter key ◀. Each time you press the enter key ◀, you see the next counter.

Backup freq (only in mode S in TREND II BILEVEL, BILEVEL ST20 and ST30)



In the event of apnea lasting longer than 15 s, the patient will continue to be ventilated with a frequency of 10 bpm and an I:E ratio of 1:2.

To activate or deactivate the Backup frequency, first go to the Clinic-menu. Then select **Backup freq** using the programming keys ▲ and ▼. The PIN code is now requested. Once you have entered the PIN, you can change the setting ("ON" or "OFF") by pressing the enter key ◀.

VT min (only in modes S, T and ST in TREND II BILEVEL ST30)



The purpose of the target volume is to safeguard the respiratory volume per breath during pressure-controlled ventilation.

To set the target volume, first go to the Clinic-menu. Then select $\forall T \; \text{min} \; \text{using}$ the programming keys \blacktriangle and \blacktriangledown . You will now be requested to enter the PIN. The first digit will flash. Use the programming keys \blacktriangle and \blacktriangledown to enter the first digit of the PIN. After pressing the enter key \blacktriangleleft , the second digit will flash. Use the programming keys \blacktriangle and \blacktriangledown to enter the second digit of the PIN, etc. After the last digit of the PIN, you can use the programming keys \blacktriangle and \blacktriangledown to set the target volume. Confirm the selected target volume using the enter key \blacktriangleleft . The parameter P-addit, is set next.

P-addit. (only in modes S, T and ST in TREND II BILEVEL ST30)

To reach the target volume, an additional pressure (P-addit.) must be set. The pressure is then increased until the target volume is reached, but no further than the additional pressure set. Once the target volume has been reached, the additional pressure is decreased again. The additional pressure is limited to 2 hPa per breath.

If the I-Pressure is set to \geq 28 hPa then the target volume is automatically set to "OFF". "P-addit." can then no longer be selected.

First set the VT min. Then set the desired value using programming keys \triangle and ∇ . To confirm, press the enter key \triangleleft .

TI min (only in modes S and ST in TREND II BILEVEL ST20 and ST30)



TI min is the minimum inspiration time. By setting of TI min a minimum duration of the inspiration is guaranteed. Breathing out before expire the set TI min is not possible.

To set the minimum inspiration time, first go to the Clinic-menu. Then select $TI \cap I$ using the programming keys A and V and press the enter key I. You will now be requested to enter the PIN. The first digit will flash. Use the programming keys I and V to enter the first digit of the PIN. After pressing the enter key I, the second digit will flash. Use the programming keys I and V to enter the second digit of the PIN, etc. After the last digit of the PIN, you can use the programming keys I and V to enter the minimum inspiration time. Confirm the selected value using the enter key I The II max parameter is set next.

TI max (only in modes S and ST in TREND II BILEVEL ST20 and ST30)



TI max is the maximum inspiration time. By setting of TI max a maximum duration of the inspiration is defined. After expiration of TI max the inspiration will be interrupted and the expiration begins.

First set TI min. Then set the desired value using the programming keys \blacktriangle and \blacktriangledown . To confirm, press the enter key \blacktriangleleft .

Low MV (only in modes S, T and ST in TREND II BILEVEL ST30)



Here you can set whether the device gives an alarm if the respiratory minute volume falls below the set value.

To set the alarm parameter "Low MV", first go to the Clinic-menu. Then set the desired value using the programming keys \blacktriangle and \blacktriangledown . To confirm, press the enter key \blacktriangleleft . If the device is in S mode and the Backup frequency is set to "OFF", the apnea parameter is set next.

Apnea (only in mode S in TREND II BILEVEL ST30, if backup freq. "OFF")



Here you can set whether the device gives an alarm if an apnea occurs which lasts longer than the set value.

First, set the alarm parameter "Low MV". Then set the desired value using the programming keys \blacktriangle and \blacktriangledown . To confirm, press the enter key \blacktriangleleft .

PARAMETER SETTINGS

Parameter	Settings range	Dependency	Settings steps	Accuracy
Press.	4-20 (30 ¹) hPa		0.5 hPa	0.5 hPa
P-Start	4-20 hPa	\geq P-Min, \leq P-Max	0.5 hPa	0.5 hPa
P-Min	4-20 hPa	≤ P-Start	0.5 hPa	0.5 hPa
P-Max	4-20 hPa	≥ P-Start	0.5 hPa	0.5 hPa
I-FLEX	0-3		1 Level	
E-FLEX	0-3		1 Level	
Mask	Nose, Nose/ Mouth			
I-Pres.	E-Pres. – 20 (30¹) hPa	≤ E-Pres. – 20 (30¹) hPa	0.5 hPa	0.5 hPa
E-Pres.	4 hPa – I-Pres.	\geq 4 hPa, \leq I-Pres.	0.5 hPa	0.5 hPa
I-Slope	0.0-1,0s	I-Pres E-Pres., ≤ I:E	0.1s	
E-Slope	0.0-1.0s	I-Pres E-Pres.	0.1s	
I-Trigger	1-3		1 Level	
E-Trigger	1-3		1 Level	
Frequency	5-30 bpm		1 bpm	1 bpm
I:E	0.4-8.0s	I-Slope, E-Slope, Frequency	0.1 s	0.1 s
Delay Time	0-20s		1 s	1 s
Backup freq	ON; OFF			
VT min ¹	OFF; 200 – 1500 ml	I-Pres. < 28 hPa	100 ml	± 20 %
P-addit. ¹	1-10 hPa	P-addit.+I-Pres. ≤30 hPa, I-Pres. <28 hPa, VT min ≥ 200 ml	0.5 hPa	0.5 hPa
TI min	OFF; 0.1 s - (TI max - 0.1 s)	TI max - 0.1 s	0,1 s	0.1 s
TI max	OFF; 0.1s-4.0s	TI min + 0.1 s	0.1s	0.1s
Ramp	0 – 60 min		1 min	1 min
P-Ramp	4 hPa – E-Pres.			
	APAP: 4 hPa – P-Start		0.5 hPa	0.5 hPa
	CPAP/FLEX: 4 hPa - Press.			
Mask Test	0-90s		5 s	1s
Auto	OFF, Start/Stop, Start			

Parameter	Settings range	Dependency	Settings steps	Accuracy
♣ Low MV ¹	OFF, 2-10 l/min		0.5 l/min	0.5 l/min
♣ Apnea ¹	OFF; 5-30s	Backup freq = OFF	1 s	1 s
Display Vt	ON, OFF			
Brightness	0-100%		10 %	
Language	DEU, ENG, ELL, SPA, FRA, ITA, NLD, TUR, PLK, POR			
P-Unit	hPa, mbar, cmH ₂ O			

¹ TREND II BILEVEL ST30

ALARM FUNCTIONS OF THE DEVICE

POWER FAILURE

If a power failure at night would go unnoticed as a result the patient would breathe used air from the therapy tube all night. To avoid this the device is equipped with an alarm mechanism that warns you if power or a fuse fail at night. You will be woken up with an acoustic signal so you can take the mask off your face and breathe fresh air. The alarm is turned off by pushing the on/off key. After power supply is re-established the motor starts automatically and the display will show the following message:

Power Failure Restart Turbine

Checking the power failure function

IMPORTANT

To check the power failure alarm, the device must have been connected to the power cord and turned on for at least half an hour.

Use the device with running blower and then pull the power plug out of the wall socket. Now the acoustic warning signal should sound. Check once a month if the signal sounds long enough (reference value: at least 3 minutes). After pushing the on/off key or turning on the power supply again the signal will stop.

MASK ALARM

This alarm function is activated only if the automatic function is turned to "OFF" or "Start". If the mask has slipped off your face or if the tube is pulled off the device, the device is not turned off automatically, but emits a visual and audible alarm.

Mask Alarm....10s Check Mask!

The alarm is silenced after pressing the on/off key or eliminating the leak.

Check Mask Alarm

Use the device with running turbine in the manual mode (automatic function "OFF" or "Start"). The mask is open but not applied to your face. After a short time, an audible signal is emitted.

PRESSURE ALARM

If during the therapy by a hardware error or other circumstances (e.g. due to a bent measuring tube) the pressure becomes too high the device will generate an alarm sound and turn off the blower.

The alarm is turned off by pushing the on/off key and the therapy can be continued after solving the error.

WAKE ALARM

The device is provided with a comfortable integrated alarm clock. Using the programming keys, you can activate and deactivate this alarm clock. The alarm clock emits an alarm at the programmed wake time.



Press the on/off key once to stop the alarm for the next 5 minutes (can be set with the help of the PC Software TRENDset) and twice to deactivate it completely.

The alarm clock function may have been deactivated through the PC Software TRENDset. Please contact your specialized dealer or service technician for activating these functions.

LOW RESPIRATORY MINUTE VOLUME (ONLY ST30)

If the respiratory minute volume falls below the set alarm parameter "Low MV", the device will gives an alarm.



The alarm is turned off by pressing the on/off key.

APNEA ALARM (ONLY ST30 IN MODE S)

If an apnea is detected which is longer in duration than the set alarm parameter "Apnea", the device gives an alarm.



The alarm is turned off by pressing the on/off key.

USING AN SD CARD

GENERAL INFORMATION

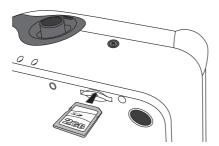
The use of an SD card during therapy enables the most important therapy data to be saved. The physician can read and evaluate this data via the TRENDset PC software. Furthermore, the physician can set new therapy parameters using TRENDset and send them to the patient. As soon as the SD card is inserted, the device adopts the therapy parameters.

IMPORTANT

Only HOFFRICHTER SD cards can be used. These has to be formatted by TRENDset (see page 75).

INSERTING THE SD CARD

- 1. If connected, disconnect the humidifier from the device.
- 2. Ensure that the device is in standby mode.
- 3. Carefully lift the device.
- 4. Insert the SD card into the SD card slot.



5. The device initializes and the message "Do not remove the SD card" is shown on the display.

Do not remove the SD card

The time required for initialization depends on the device settings.

NOTICE

On no account remove the SD card during initialization. This could lead to loss of data or damage to the SD card.

6. After initialization, the message disappears. If the SD card contains new therapy parameters, these parameters are adopted by the device and the message "New Parameters were accepted" is displayed.

New Parameters were accepted

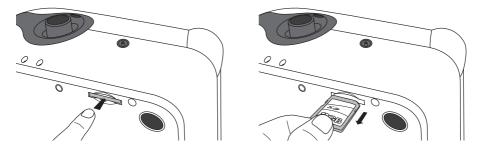
7. By pressing the enter key ◀ or after 10 s the message will be disappear.

IMPORTANT

After the takeover of the parameters enter the Info-Menu and compare the displayed parameters with the values of your prescription.

REMOVING THE SD CARD

- 1. If connected, disconnect the humidifier from the device.
- 2. Ensure that the device is in standby mode.
- 3. Carefully lift the device.
- 4. Carefully push the SD card into the card slot and remove the SD card.



NOTICE

Only remove the SD card in standby mode (see page 25). Otherwise data may be lost or the SD card damaged.

WHAT IS SAVED ON THE SD CARD

The last 100 events are saved on the SD card. Events are changes of parameters such as therapy settings, resetting counters (e.g., filter counters) etc. The parameters are saved with the date and time they were changed, as well as the old and new value. All alarms that occurred are also saved with date and time.

The SD card can only be read using the TRENDset PC software.

The following therapy-related events are also saved on the SD card:

Device type Parameter	CPAP	APAP	BILEVEL	BILEVEL ST20	BILEVEL ST30
Pressure	•	•	•	•	•
Respiratory Flow	•	•	•	•	•
Average System Flow (Leakage Flow)	•	•	•	•	•
Hyperventilation	•	•	•	•	•
Leakage	•	•	•	•	•
Mode	•	•	•	•	•
Frequency	•	•	•	•	•
Relative Respiratory Tidal Volume	+	•	-	+	-
Central Sleep Apnea	-	•	-	-	-
Obstruktive Sleep Apnea	-	•	-	-	-
Mixed Sleep Apnea	-	•	-	-	-
Hypopnea	•	•	-	-	-
Apnea	•	-	•	•	•
Airway Constriction	-	•	-	=	-
Snoring	-	•	-	-	-
General Artifact	-	•	-	=	-
Adjustment	•	•	•	•	•
Mouth Exhalation	-	•	-	-	-
Tidal Volume	•	-	•	•	•
Apnea alarm	-	-	-	-	•
Low MV	-	-	-	-	•

ERROR MESSAGES

Two different types of error are distinguished: errors with data loss and errors without data loss.



The display "Exx" denotes errors in which data may have been lost. The display "Wxx" denotes errors in which no data has been lost.

To hide an error message, press the enter key ◀.

NOTICE

If error messages occur frequently, we recommend that the device is examined by a service technician.

IMPORTANT

If you carry out the therapy without recording the therapy data, we recommend not using an SD card in the device, in order to avoid unnecessary error messages.

The following table shows all error codes that can occur in connection with the use of the SD card.

Error code	Meaning	Remedy
E00	Writing data has failed. Possible causes are power failure, removal of card during writing or a faulty SD card.	The SD card is probably faulty. Remove the SD card and then insert it into the device again. If the error continues to occur, send the card back to the physician.
E01	The SD card is faulty.	Obtain a new SD card from your physician or specialist dealer.
E02	File system or folder structure is faulty or cannot be read.	The SD card must be formatted by the physician using TRENDset.
E03	New files cannot be created or the SD card is full.	The SD card must be formatted by the physician using TRENDset.
E04	The device cannot adopt the therapy data.	The SD card must be returned to the physician to check the therapy.
E05	The SD card was removed.	Insert the SD card again.
	The SD card has fallen out of the card slot.	If this occurs frequently, the device should be examined by a service technician.
E06	The SD card or the device is faulty.	Change SD card. If this occurs frequently, the device should be examined by a service technician.
W00	The device is attempting to repair the SD card. But you have inserted a new SD card into the device.	Confirm with key ◀. The old SD card is defective. Continue to use the new SD card.
W05/06	see error code E05/E06	see error code E05/E06

IMPORTANT DISPLAY MESSAGES

The sections below describe the most important display messages. All further messages will be clear from their context.



You have 45 sec left for seating the mask properly. Once this time has elapsed, the device starts with the soft start function or the therapy.



There will be 10 min and 45 sec left until the full therapy pressure is reached.



You have activated the display of the respiratory volume and the wake up alarm

Mask Alarm....10s Check Mask! The mask has slipped off your face or you failed to put the mask on your face while the automatic mode was turned off and the blower was running.

Press ON/OFF! Alarm ON 07:00 You pressed the programming key ▲ during operation. There will be a message that you will be wakened at 07.00 o´clock.



There will be 1 min and 18 sec left until the alarm clock will awake you again.

∭∭ 5.0hPa Wake Alarm 07:00 The wake alarm has been initiated. Press the on/off key once to initiate the slumber phase. Press the key once again to turn off the alarm completely.

∭ 5.0hPa Wake Alarm OFF You have pressed the on/off key and stopped the slumber phase.

Press ON/OFF! Alarm Clock OFF You pressed the programming key ▼ in the normal operating mode. There will be a message that the alarm clock has been turned off.

Press too high 25.May.11 21:33 The therapy pressure is too high and the turbine switches off.

Put on Mask! 25.May.11 22:15 The automatic function is turned on. You will be requested to put on the mask and breathe.

Power	Failure
Restar	t Turbine

After the line voltage has been restored, the turbine restarts automatically.

Watchdos defect

There has been an error during the system start after switching on the voltage supply. **Contact your dealer**.

Turbine off....4s 25.May.11 07:01 You have taken down the mask or the mask has slipped off your face while the automatic function was activated. The turbine will turn off after 4 seconds.

Invalid PIN!

The PIN you have entered is wrong. Please enter the correct PIN.

MemoryF defect

There has been an error during the system start after switching on the voltage supply. **Contact your dealer.**

Clinic-Menu active The Clinic-Menu has been activated.

Patient-Menu active The Patient-Menu has been activated.

5.0hPa Change Filter Change filter cassette (see page 68).

CHANGING THE FILTER CASSETTE, CLEANING

AWARNING

Make sure that you follow the cleaning instructions. If you do not do this, it could damage your health because of germs.

CHANGING THE FILTER CASSETTE

ACAUTION

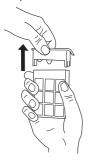
If the filter is polluted or the display shows the message Change Filter the filter cassette must be changed.

To change the filter cassette, proceed as follows:

1. To change the filter cassette, pull it out of the device.



2. Separate filter cassette and filter frame cover by pulling them apart.



3. Replace the filter cassette by a new one. Mount the filter frame cover onto the new filter cassette. Make sure the upper part (slit) and the filter cassette (pin) are in the correct position.



To set back the message proceed as described in the chapter "Patient-Menu" on page 36.

NOTICE

Never operate the device without a filter cassette. Only and exclusively use original HOFFRICHTER filter cassettes.

CLEANING THE MASK

For reasons of hygiene the mask should be cleaned daily:

- 1. Disconnect the mask from the therapy tube.
- 2. Clean the mask with mild soapy water. Do not use any other agents!
- 3. Rinse the mask thoroughly with clear water.
- 4. Let the mask dry completely in the air.

CLEANING OF THE THERAPY TUBE

For reasons of hygiene the therapy tube should be cleaned weekly. Make sure the measuring tube is unobstructed at all times. Avoid ingress of water into the measuring tube during the weekly cleaning. If water droplets should have accidentally entered the measuring tube they must be carefully and thoroughly removed.

- 1. Close the measuring tube tightly with the tube plugs before cleaning.
- 2. Clean the therapy tube with mild soapy water. Do not use any other agents!
- 3. Rinse the therapy tube thoroughly with clear water.
- 4. Let the therapy tube dry completely in the air.
- 5. After cleaning, remove both of the tube plugs from the measuring tube.

NOTICE

If water should stay in the measuring tube it could adulterate the pressure measuring or delay the control. Both could affect an optimal therapy.

CLEANING THE DEVICE

For reasons of hygiene, the device should be cleaned weekly:

- 1. Unplug the power plug.
- 2. Wipe the device with a cloth slightly dampened with soapy water.
- 3. Rub the device dry with a cloth.

IMPORTANT

Chemical or thermal disinfecting of the device or the device parts by the user is not necessary.

CLEANING THE HEAD GEAR

Clean the head gear as required:

- 1. Disconnect the head gear from the mask.
- Clean the head gear as described in the head gear manufacturer's User's manual.

CLEANING THE HUMIDIFIER

AWARNING

When using a humidifier, the cleaning instructions in the user's manual must be observed.

TROUBLESHOOTING

Problem	Possible cause	Remedy
Pain in the nose, the para- nasal sinuses or the ears	Inflammation of the para- nasal sinuses or the middle ear	Stop the treatment and contact your physician
Feeling, that the pressure is too high	Malaise with prescribed high pressure values	If you suspect an error, please ask your physician for help
	Acclimatisation phase to the pressure not yet completed	Try to relax. Use or vary the soft start function
Dryness and irritation in the nose and throat	Air is too dry	Device probably does not have an air humidi- fier. Speak to your physi- cian about retrofitting an humidifier
Original symptoms of sleep apnea come back	Physical condition or life circumstances have changed	Inform your physician
	Device error	Have the device checked by customer services
Irritated or dry eyes	Air escapes between the mask and the skin of the	Check the mask for proper positioning
	face	Check the positioning of the mask
Cold nose	Room temperature too low	Replace the mask if the material has become chapped
Runny nose, sneezing	Reaction to the air flow	Either increase the humidity in the room or the temperature of the humidifier
	Normal cold	Contact your physician
Reddening of the skin in	Incorrect mask size	Inform your physician
the mask area, skin swelling	Headgear too tight	Loosen the headgear
SWGIIII IY	Allergic reaction	Inform your physician
Feeling that the air is too hot	Filter dirty	Change the filter cassette
	Air inlet blocked	Change the position of the device. Keep the air inlet clear
	Heater close to the device	Move the device and the heater further apart

Problem	Possible cause	Remedy
No air flow	Device is defective	Inform customer services
	Water in the measuring tube	Remove the water
Very little air flow	Soft start function has been selected	Reduce soft start time
	Air channels are blocked	Check air inlet
Blower is running constantly at maximum speed	Measuring tube not connected or clogged	Check the measuring tube
	Leak in the device	Have the device checked by customer services
	Water in the measuring tube	Remove the water
Therapy pressure not	Water in the measuring tube	Remove the water
steady	Device defective	Notify the service
	Measuring tube bent	Check for bends

MAINTENANCE

If operated correctly, the device is maintenance-free. However, in order to increase the service life, we recommend regular maintenance every 2 years.

▲ CAUTION

Do not try to open the device. Maintenance and repairs may only be performed by personnel authorized by us, because only they have the tools and measuring equipment required.

You yourself can help to increase the service life of the device and ensure that it continues to work safely.

- Follow the cleaning instructions from page 68.
- Check the system regularly:
 - Conduct a visual check for external damage and dirt
 - Check the alarm function "Power failure" (see page 59)
 - Check the alarm function "Mask alarm" (see page 59)

PREPARING THE DEVICE WHEN CHANGING PATIENT

The devices are only intended for use by a single patient.

ACAUTION

If the device is to be used for another patient, it must first of all be prepared hygienically.

When being given to another patient, the device must be prepared hygienically by the specialist dealer or the manufacturer. If reuse of the mask and the therapy tube is planned, they must also be prepared by the specialist dealer or the manufacturer.

The preparation procedure is described in detail in the corresponding hygiene plan.

DISPOSAL

Proper disposal saves natural resources and prevents harmful substances being released into the environment.

DEVICE



The device must not be disposed of with the household waste. Please contact the relevant customer services department to find out how to dispose of the device properly.

PACKAGING



The packaging is taken back by the distributor but it can alternatively be recycled.

ACCESSORIES

The accessories like the tubing, mask, filter cassettes, etc. should be disposed according to the manufacturer's instructions, or with normal household waste.

ACCESSORIES

Scope of delivery	Article number
TREND II CPAP	0000 2061
TREND II AUTO	0000 2064
TREND II BILEVEL	0000 2062
TREND II BILEVEL ST20	0000 2063
TREND II BILEVEL ST30	0000 2035
Carrying case	0000 2437
Power supply cable (approx. 2.30 m)	31100015
Filter cassette	0000 2058
Therapy tube (1.80 m), measuring tube and tube plugs	00007116
SD card, formatted with TRENDset	1120 0010
User's manual	5000 0427
Brief instruction	5000 0434

Optional	Article number
Standard Nasal Mask, Size S	00003440
Standard Nasal Mask, Size M	00003434
Standard Nasal Mask, Size L	0000 3435
Standard Full Face Mask, Size S	00003441
Standard Full Face Mask, Size M	0000 3436
Standard Full Face Mask, Size L	00003437
Cirri Mini Comfort Nasal Mask, Child-S	00003551
Cirri Mini Comfort Nasal Mask, Child-M	00003552
Cirri Mini Comfort Nasal Mask, Child-L	0000 3498
Cirri Comfort Nasal Mask, Size XS	0000 3497
Cirri Comfort Nasal Mask, Size S	0000 3486
Cirri Comfort Nasal Mask, Size M	00003487
Cirri Comfort Nasal Mask, Size L	0000 3488
Cirri Comfort Full Face Mask, Size S	0000 3483
Cirri Comfort Full Face Mask, Size M	00003484
Cirri Comfort Full Face Mask, Size L	0000 3485
Nasal Pillow 4in1, Sizes XS, S, M, L	00003499
ComfortTube System (heated tubing system)	00003479
Humidifier AquaTREND uni	0000 2073
Filter cassette with frame cover	0000 2057
O ₂ supply adapter	0000 4943
O ₂ pressure valve	0000 4947
24 V DC vehicle cable	0000 9212
12 V to 24 V converter	0000 7133

For ordering of accessories, please contact a HOFFRICHTER service partner.

TECHNICAL DATA

	TREND II						ND II TREN	with ID uni		
Dimensions (WxDxH)	215 x 195 x 105 mm				215 x 320 x 125 mm					
Weight			2.3 kg	3		2.65 kg (without water)				
Power supply		100	V~	240 V	~, 50	. 60 Hz	, 24 V	DC/	2.1 A	
Mains power			1	00 2	240 V A	C, 50	60 ⊦	łz		
DC power				2	24 V D0	2/2.1	4			
Operating time under battery power					up to 8	3 years				
Pressure range	4	l20 l	nPa (m	nbar); E	BILEVE	L ST3	D: 4	30 hPa	a (mbar	r)
Max. limit pressure in the event of a fault		≤40	hPa (I		,	PAP - A LEVEL	,	und S	ST30)	
Power consumption	DC	powe	r N	1ains p	ower	DC	powe	r N	/lains p	ower
Standby	<	5 W		< 5\	Ν					
Operation at 12 hPa	-	10 W		< 12		<30 W <33 W				
Short term pressure va										
	4 hPa	8 hPa	12 hPa	16 hPa	20 hPa	4 hPa	8 hPa	12 hPa	16 hPa	20 hPa
10 bpm		0.09			0.09				0.11	
15 bpm		0.22			0.21				0.23	
20 bpm	0.41	0.36	0.45	0.34	0.33	0.45			0.38	0.36
01	! _ #!	- TDC	UD II E		LOTO) : I- D		ating	evel 3)	
Short term pressure v	ariatior 4	10,5	אטוו ב 17	23.5	L S130) IN NP 4	a 10.5	17	23.5	30
	4 hPa	hPa		bPa	hPa	hPa		hPa	hPa	hPa
10 bpm		0.12		0.13	0.19	0.13			0.13	0.13
15 bpm	0.28	0.24	0.22	0.23	0.28	0.30	0.22	0.22	0.23	0.24
20 bpm	0.48	0.42	0.39	0.39	0.48	0.43	0.35	0.37	0.37	0.37
	(at heating level 3)									
Long term pressure variation	± 0.3 hPa									
Pressure reading accuracy	0.5 hPa									
Average sound pressure level (operating at 1 m distance)		\leq 26 dB(A) at 10 hPa (equivalent to a sound power level of \leq 34 dB[A])								

	TREND II	TREND II with AquaTREND uni		
Air flow rate TREND II	CPAP, AUTO, BILEVEL, BILEVE	L ST20		
4 hPa	208 l/min	183 l/min		
8 hPa	198 l/min	176 l/min		
12 hPa	188 l/min	166 l/min		
16 hPa	177 l/min	155 l/min		
20 hPa	164 l/min	144 l/min		
Air flow rate TREND II	BILEVEL ST30			
4 hPa	215 l/min	209 l/min		
10.5 hPa	204 l/min	197 l/min		
17 hPa	195 l/min	188 l/min		
23.5 hPa	181 l/min	174 l/min		
30 hPa	175 l/min	158 l/min		
Operating temperature	+5°C+32°C (Ambient temperatures up to 40°C does not harm the device function at all.)			
Storage/Transport temperature	- 20 °C .	+70°C		
Therapy air heating	<3 K	depending on the heating level and the ambient conditions		
Relative humidity	15 % 95 % for op	peration and storage		
Ambient air pressure range Storage/Transport Operation	1060 hPa 265 hPa (approx 400 m 10000 m) 1060 hPa 800 hPa (approx 400 m 2000 m) ¹			
Filter	Polyurethane foam on poly	vester base, 80 ppi, 30 kg/m³		
Therapy tube connection	22 mm, cone (gem. ISO 5356-1)			
Product class according to 93/42/EEC	lla			
Classification according to EN 60601-1	Protection class II			
With increasing altitude, the air flow rate decreases.				

Therapy			Device type		
parameter factory settings	CPAP	AUTO	BILEVEL	BILEVEL ST20	BILEVEL ST30
Mode	FLEX	APAP	S	ST	ST
Press.	6,0 hPa				
P-Start		6,0 hPa			
P-Min		4,0 hPa			
P-Max		10,0 hPa			
I-FLEX	2	2			
E-FLEX	2	2			
Mask		Nose			
I-Pres.			10,0 hPa	10,0 hPa	10,0 hPa
E-Pres.			6,0 hPa	6,0 hPa	6,0 hPa
I-Slope			0,3s	0,3s	0,3s
E-Slope			0,3s	0,3s	0,3s
Trigger					
I-Trigger			2	2	2
E-Trigger	-+-		2	2	2
Frequency				12 bpm	12 bpm
I:E				2,0 s	2,0 s
Delay Time				5s	5 s
Backup freq			OFF		
VT min					OFF
TI min				OFF	OFF
TI max				OFF	OFF

Alarm parameter factory settings TREND II BILEVEL ST30				
Low MV	OFF			
Apnea	OFF			

Comfort parameter factory settings for all device types				
Ramp	0 min			
Mask Test	Os			
Auto	OFF			
Display Vt	OFF			
Brightness	50 %			
P-Unit	hPa			

CE marking as per EC directive 93/42/EEC.

The manufacturer reserves the right to make technical changes without notice.

MANUFACTURER'S DECLARATION ON ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration - electromagnetic emissions

The TREND II is intended for use in the electromagnetic environment specified below. The user¹ of the TREND II should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions acc. to CISPR 16-1-2	Group 1	The TREND II uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions acc. to CISPR 16-1-2	Class B	The TREND II is suitable for use in all establishments including those directly connected
Harmonic emissons acc. to IEC 61000-3-2	Class A	to the public low-voltage power supply net- work that supplies buildings used for domes-
Voltage fluctuations / flicker emissions acc. to IEC 61000-3-3	Complies	tic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity

The TREND II is intended for use in the electromagnetic environment specified below. The user ¹ of the TREND II should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environ- ment – guidance
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 8 kV air	± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst acc. to IEC 61000-4-4	± 1 kV input/output	± 1 kV input/output	Mains power quality should be that of a typical commer- cial or hospital environment.
Surge acc. to IEC 61000-4-5	± 1 kV volt- age differential mode	± 1 kV volt- age differential mode	Mains power quality should be that of a typical commer- cial or hospital environment.

Here user is meant in the sense of "Responsible Organization"

Guidance and manufacturer's declaration – electromagnetic immunity					
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance		
Voltage dips, short interruptions and volt- age variations on power supply input lines acc. to IEC 61000-4-11	100 % dip in U_T for 0.5 cycle 60 % dip in U_T for 5 cycles 30 % dip in U_T for 25 cycles 100 % dip in U_T for 5 s	100 % dip in U_T for 0.5 cycle 60 % dip in U_T for 5 cycles 30 % dip in U_T for 25 cycles 100 % dip in U_T for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TREND II requires continued operation during power mains interruption, it is recommended that the TREND II is powered from an uninterrupted power supply (UPS) or a battery.		
Power frequency (50/60 Hz) magnetic field acc. to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.		
Conducted RF acc. to IEC 61000-4-6	V ₁ = 3 V 150 kHz – 80 MHz	3 V	Portable and mobile communications equipment should be used no closer to any part of the TREND II, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended safety distance: d = 1.17 √P		

Guidance and manufacturer's declaration - electromagnetic immunity

Radiated RF acc. to IEC 61000-4-3	E ₁ = 3 V/m 80 MHz – 2.5 GHz	3 V/m	d = 1.17 \sqrt{P} for 800 MHz to 800 MHz d = 2.33 \sqrt{P} for 800 MHz to 2.5 GHz with P as the rated maximum output power of the transmitter in watts (W), according to the transmitter's manufacturer, and d as the recommended safety distance in meters (m).
			Field strengths from fixed RF transmitters,

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a, should be less than the compliance level in each frequency range ^b.

Interference may occur in the vicinity of equipment marked with the following symbol.



- Note 1 U_T is the mains alternating current before application of the test level.
- Note 2 At 80 MHz and 800 MHz the higher frequency range is essential.
- Note 3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- The field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the location in which the TREND II is used exceeds the compliance level, the TREND II should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the TREND II.
- b Over the frequency range from 150 kHz to 80 MHz the field strength should be lower than 10 V/m.

Recommended separation distances between portable and mobile RF communication equipment and the TREND II

The TREND II is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user¹ of the TREND II can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TREND II as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz – 80 MHz $d = 1.17 \sqrt{P}$	80 MHz – 800 MHz $d = 1.17 \sqrt{P}$	800 MHz – 2.5 GHz $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz the higher frequency range is essential.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Here user is meant in the sense of "Responsible Organization"

DISCLAIMER

HOFFRICHTER GmbH is not liable for consequences in terms of safety, reliability and performance of the product where:

- interventions, modifications, extensions, calibration, repairs and maintenance are carried out by persons not authorized by us,
- other manufacturers' accessories and spare parts are used that have not been approved by us for use on the product,
- the product is used other than as described in the user's manual or
- the hygiene and cleaning instructions described in the user's manual have not been complied with.

Statutory guarantee rights remain unaffected by this.